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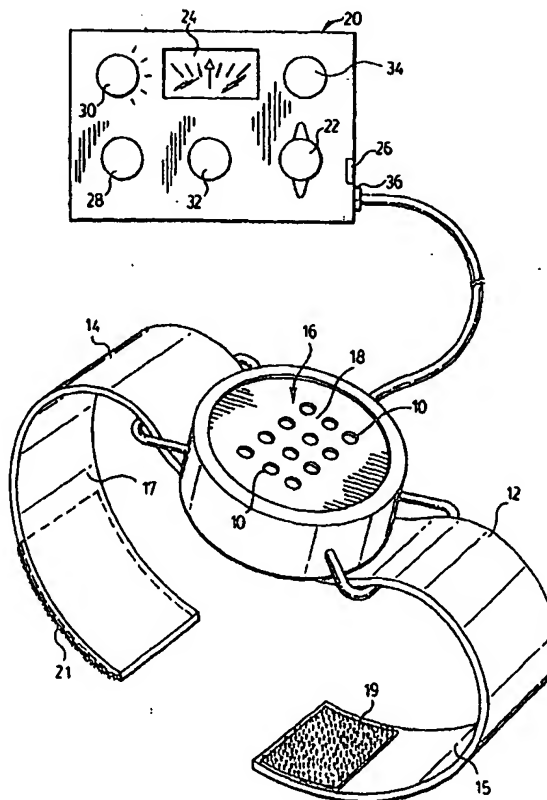
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : A61N 5/06</p>	<p>A1</p>	<p>(11) International Publication Number: WO 99/42178 (43) International Publication Date: 26 August 1999 (26.08.99)</p>
<p>(21) International Application Number: PCT/CA99/00156 (22) International Filing Date: 22 February 1999 (22.02.99) (30) Priority Data: 60/075,671 23 February 1998 (23.02.98) US (71) Applicant (for all designated States except US): LASER RESEARCH INTERNATIONAL, INC. [CA/CA]; 2910 South Sheridan Way, Oakville, Ontario L6J 7J8 (CA). (72) Inventor; and (75) Inventor/Applicant (for US only): PASSY, Philip, W. [CA/US]; 467 Yacht Club Road, Hartwell, GA 30643 (US). (74) Agent: WOODLEY, John, H.; Sim &amp; McBurney, 6th floor, 330 University Avenue, Toronto, Ontario M5G 1R7 (CA).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>

(54) Title: THERAPEUTIC CLUSTER LASER DEVICE

## (57) Abstract

A cluster laser device comprises a cluster laser unit and a strap for attachment to the body. The cluster laser unit typically has 10 to 20 low-powered laser diodes arranged in a cluster. The device may be used in place of acupuncture needles and in human and veterinary medical treatments. This invention has the advantage of being conveniently attachable, lightweight and portable and can be used to treat larger surface areas than traditional laser therapy devices.



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## THERAPEUTIC CLUSTER LASER DEVICE

**FIELD OF THE INVENTION**

The invention is concerned with the use of lasers in low energy photon  
5 physiological therapy. A cluster of low energy emitting lasers are provided in a  
portable unit for the treatment of a wide range of soft tissue and  
musculoskeletal injuries. The cluster laser system is also applicable to the  
field of acupuncture.

**BACKGROUND OF THE INVENTION**

10 Lasers have long been used in medical applications including  
diagnosis and treatment of various disorders. The surgical and cosmetic  
utilization of lasers as well as their use in photodynamic therapy of cancer are  
well known. Low powered lasers which emit approximately 10,000 times less  
energy than surgical lasers have been used for the treatment of soft tissue  
15 injuries such as sports injuries, repetitive strain injuries, whiplash and chronic  
back pain. Low power lasers have also been used to imitate the fine needles  
normally associated with acupuncture treatment as well as to accelerate  
wound healing. These lasers have several beneficial effects which are  
mediated by various mechanisms. A well known mechanism is the conversion  
20 of light energy into chemical energy. Photons of light from a laser penetrate  
into the tissue and accelerate the synthesis of adenosine triphosphate (ATP).  
ATP is a major carrier of energy from one chemical reaction to another within  
the cells of the body. Thus an increase in the amount of ATP in a cell results  
in an increase of available energy that can be directed towards healing  
25 damaged muscle cells. It has been reported that the time for healing can be  
reduced by as much as 2/3rds of the normal healing time. The extra energy  
can also be used by fibroblasts to increase collagen production. Collagen is  
required to replace old tissues and repair tissue injuries. Studies have also  
shown that the energy derived from the laser increases the activity of the ATP  
30 dependent Na-K pump. This increased activity results in an increase in the  
potential difference across the cell membrane, moving the resting potential  
further from the firing threshold, thus, decreasing nerve ending sensitivity. It  
has also been postulated that laser light may result in the production of

naturally occurring pain-killing molecules such as endorphins and enkephalins in the brain. It has also been shown that treatment with laser light increases blood flow and increases the formation of new capillaries in damaged tissue. This speeds up the healing process, closes wounds quickly and reduces scar  
5 tissue. There is also evidence suggesting that low power laser light can speed up the regeneration of the lymphatic system.

It has been common practice to apply laser light to a patient by moving a wand-like apparatus over the affected area. Frequently, this treatment is administered in hospitals or through outpatient services. It is often time  
10 consuming due to the small area that can be treated at a time. The present invention overcomes these problems by providing a low-power laser source that provides a comparable intensity of photon energy through a plurality of low power lasers arranged in a cluster. The apparatus is adapted to be portable and can be used in the home, thus providing increased convenience  
15 for the patient and a reduction in health care costs.

#### **SUMMARY OF THE INVENTION**

This invention is concerned with a cluster laser pack designed for use in either human or veterinary applications. The invention is light weight and portable and can be used to treat soft tissue injuries, chronic pain and other  
20 laser treatable conditions. This invention may also be used to simulate the fine needles of acupuncture.

In one aspect of the invention, a cluster laser unit comprises a plurality of cold-powered laser diodes mounted in a portable unit. In a preferred embodiment, from about 10 to about 20 laser diodes emitting from about 1 to  
25 about 50 milliwatts each are mounted in a unit having a backing. The laser unit is a component of a device including means of attaching to the body. In a preferred embodiment the laser unit is provided on a flexible strap having velcro-type fasteners. This embodiment allows for the laser to be applied or strapped in an efficient manner to various body parts such as elbows, knees,  
30 etc. that are not typically flat.

A method of utilizing the cluster laser unit device is also provided. The cluster laser device may be used to simulate the fine needle points of acupuncture therapy or in veterinary or human laser therapy.

According to another aspect of the invention, a single laser may be substituted for the cluster laser, where the single laser is used in combination with a laser light dispersion multiplier device.

Other aspects of the present invention are as follows:

A portable phototherapy apparatus adapted for attachment to at least one body part comprising:

- i) means for providing dispersed photons over a predetermined surface area
- ii) means for attaching said apparatus to a body part; and
- iii) control means for adjusting the intensity and duration of therapy.

The use of a plurality of cold powered laser diodes to stimulate photochemical reactions in an area to be treated, wherein said area to be treated is selected from the group consisting of wrist, elbow, shoulder, back, neck, ankle or knee.

#### **DESCRIPTION OF THE DRAWINGS**

A preferred embodiment of this invention is illustrated in the accompanying drawings, in which like numerals denote like parts throughout, and in which:

Figure 1 is a schematic drawing of the cluster laser device and its control panel.

Figures 2a and 2b are a schematic of the controller unit of the present invention.

Figures 3a and 3b are a schematic of the control logic box of the present invention.

In the drawings, preferred embodiments of the invention are illustrated by way of example. It is to be expressly understood that the description and drawings are only for the purpose of illustration and as an aid to understanding, and are not intended as a definition of the limits of the invention.

**DETAILED DESCRIPTION OF THE INVENTION**

Laser treatment stimulates photochemical reactions which may have beneficial effects on the body such as enhanced healing or pain control. As opposed to other forms of treatment such as some types of chiropractic or drug treatment which are ongoing, laser therapy has permanent effects. This invention allows treatment over an area larger than traditional single probe or wand arrangements. In addition, the current invention is more user friendly as it can be attached to the area to be treated such as an elbow, lower back or ankle.

10 In one aspect of the invention illustrated with respect to Figure 1, a plurality of low power laser diodes 10 are provided on an adjustable Velcro® belt 12 to provide the laser cluster device 14. The Velcro belt comprises two straps 15 and 17 with a hook fastener 19 and an extra long loop fastener 21. The belts are overlapped to surround the body part and then the components 15 19 and 21 compressed to provide a secure fit. Typically, between about 10 to about 20 laser diodes are arranged in a cluster. The laser diodes have the following features. They may vary in output from about 1 milliwatt to about 50 milliwatts. The wavelength varies from about 600 to 1000 nanometers depending upon the application. Thus the emitted light may be visible or 20 infrared. The spot size varies from about 0.3 cm<sup>2</sup> to about 0.05 mm<sup>2</sup>. The laser diode may belong to various classes (i.e. Class I to Class III). In a preferred embodiment, Class IIIB lasers are implemented but it is clearly apparent that lasers of any Class may be substituted depending upon the type of application for which it is to be used (i.e. human or veterinary, wound 25 healing, pain relief, etc.). Beam divergence varies from about 10 to about 30 degrees and the power density varies from about 10 mw/cm<sup>2</sup> to about 1000 mw/cm<sup>2</sup>.

The laser diodes 10 are mounted in a protective housing 16 including a backing 18. The housing unit 16 is in communication with a controller unit 20. 30 The controller unit 20 includes an on/off switch 22 and an emission indicator 24. Power to the control panel is supplied either via an optional battery pack

or through connection to a 110 volt power supply via port 26. The emission indicator 24 provides immediate feedback with regards to the amount of energy being emitted. This level can be adjusted by means of a volume adjustment control knob 28. A timer switch 30 can be set to automatically  
5 turn off the laser unit 16 after a preset time to ensure appropriate treatment length. A manual reset button 32 and a test mode switch 34 are also provided. A remote interlock connector 36 is furnished as a safety feature.

Turning to Figures 2a and 2b, a schematic of the controller unit of the present invention.

10 The port 26 comprises an ac male plug 40. The plug 40 is connected to a step down transformer 42 which causes the voltage provided by the power supply to be lowered. This ensures that the numerous parts in the laser cluster device do not over heat or get ruined. The transformer 42 is in turn connected to a set 44 of four diodes 46, 48, 50 and 52. Diodes 46 and  
15 48 are placed in parallel arrangement with diodes 50 and 52 however, they are facing opposite directions. A location 54 between diodes 46 and 48 is connected to ground and a location 56 between diodes 50 and 52 is connected to a power division section 58. In this section 58, the power from the lower voltage provided from the transformer 42 is further divided into a  
20 laser power section 60 and a logic power section 62. It will be understood by one skilled in the art that the laser power section provides power (or voltage) to the laser diodes 10 and the logic power section provides power (or voltage) to a control logic box 64.

For the laser power section 60, the voltage from the transformer enters  
25 a laser voltage in port 66 which is located in a laser regulator 68. The voltage from the transformer 42 is also connected to ground via a pair of parallel capacitors 70 and 72. The laser regulator 68 also includes a laser ground port 74 (connected to ground) and a laser voltage out port 76 (connected to ground via a laser capacitor 78 and connected to a laser high voltage location  
30 80).

For the logic power section 62, the voltage from the transformer enters a logic voltage in port 82 which is located on a logic regulator 84. The voltage from the transformer 42 is also connected to ground via the pair of parallel capacitors 70 and 72. The logic regulator 84 also includes a logic ground port 5 86 (connected to ground) and a logic voltage out port 88 (connected to ground via a logic capacitor 90 and connected to a logic high voltage location 92).

Power is provided to the control logic box 64 by the logic high voltage location 92. A resistor 96 lies in a path between the control logic box 64 and 10 the logic high voltage location 92. The logic box 64 is also connected to a base region 96 of a Bipolar Junction Transistor (BJT) 98. An emitter region 100 of the BJT 98 is connected to a reverse-biased diode 102 which, in turn, connects to the logic high voltage location 92. The logic high voltage location 92 is also connected via a solenoid 89 to the emitter region 100 of the BJT 98 15 Contacts 91 and 93 provide the on/off switch 22. A first contact point 97 is connected to the emitter region 125 of a BJT 128 while a second contact point 99 is connected to the control connector 104. As will be described below, the operation of all the sets of laser diodes is the same and thus connection of the first contact point 97 with emitter region 125 of BJT 128 is 20 the same for each set (although not numbered in Figures 2a and 2b). A resistor 95 is placed in the path between the second contact point 99 and the control connector 104. In order for the controller unit 20 to operate, the first and second contact points 97 and 99 be connected (or contacting each other). When the first and second points 97 and 99 are connected, the 25 contact 91 is connected to the laser high voltage location 80 and therefore power (or voltage) is provided to the laser diodes.

A first contact point 101 of contact 93 is connected to the control logic box 94 while a second contact point 103 of contact 93 is not used. When the first and second contact points 101 and 103 are connected (or contacting 30 each other), the contact 93 is connected to the control logic box 64.



The control logic box 64 is also connected to a one minute timer 108 , a control connector 104 and a decade counter 106. The decade counter 106 is further connected to the one minute timer 108 which in turn is connected to an oscillator 110. By combining the functions of the decade counter 106 and  
5 the one minute timer 108, a practitioner is able to pre-set the length of time (in minutes) to apply laser therapy. The maximum limit of time is dependent on the capabilities of the decade counter. It will be understood that the decade counter need not have the capability of counting to high numbers since the laser therapy should not last more than 4 hours at a time. Usual therapy may  
10 last for approximately 5 – 20 minutes. However, if multiple parts of the body are being treated, the timer decade counter may have to count down from higher numbers. The decade counter 106 is also connected to a display 112 via a display connector 114. The display allows the practitioner to know when the treatment is finished and also to set the timer initially. The display also  
15 provides the practitioner with a reading as to the level of treatment. It will be understood that the display 112 could provide the practitioner with more information than listed above. The display connector 114 is also connected to the control logic box 64. Use of the control logic box 64 allows the practitioner the capability to keep track of the treatment being applied.

20 In the preferred embodiment, the control logic box 64 is also connected to six sets of laser diodes 10. Although six sets are described in the preferred embodiment, it will be understood that any number of sets may be provided by the present invention. By providing more than one set of outputs, the practitioner can apply the laser therapy to a larger treatment area. In the  
25 present embodiment, the control logic box 64 controls all of the sets of laser diodes 10 but it will be understood that separate controls may be provided for each set of laser diodes 10. This allows the practitioner to concurrently provide different levels of treatment to multiple treatment areas.

It will be understood by one skilled in the art that although the following  
30 description deals with the operation of one set of laser diodes control of each set of laser diodes is the same and therefore a description of all six sets of laser diodes is not necessary.

The control logic box 64 is connected to a port 115 on a chip 116 which contains 6 ports. The chip 116 provides the connection between the laser diodes and the controller unit 20. A second port 118 on the chip 116 is connected to the laser high voltage point 80 while two other ports 120 and 122 are connected directly to ground. A fifth port 124 is not used and a final port 126 is connected to a collector region 127 of a BJT 128. A base region 130 of the BJT 128 is connected to an emitter region 132 of a second BJT 134 via a resistor 136. A collector region 138 of the second BJT 134 is connected to ground. A base region 140 of the second BJT 134 is connected to the control logic box 64. The control logic box 64 signals the chip 116 to begin the therapy and after the pre-set time has been elapsed, signals the to stop the therapy.

In operation, the contact points 97, 99 of contact 91 and the contact points 101 and 103 of contact 93 must be connected in order for the controller unit 20 to operate. Contact 91 sends power (or voltage) from the laser high voltage location 80 to the emitter region 125 of the BJT 128. After receiving a signal from the control connector 104, the control logic box 64 sends a signal to the base region 140 of the BJT 134 in order for the BJT 134 to be operational. By providing these values, the control logic box 64 is able to control the set of laser diodes.

Turning to Figures 3a and 3b, a schematic is shown of the control logic box.

Within the control logic box 64, a Q input port 149 of a first flip flop 150 is connected to BJT 96 via a resistor 152. A Q-bar input port 154 of the first flip flop 150 is connected to the one minute timer 108. An S port 155 is connected to an output of a NOT logic gate 188 and to a diode 190 which, in turn, is connected to a clock port 168 of a second flip flop 170. The functions of logic gates and flip flops used in the control logic box 64 will be understood by those skilled in the art. A Reset port 156 and a D output port 158 of the first flip flop 150 are connected to ground. A clock port 160 of the first flip flop 150 is connected to an output of a NOT logic gate 162. Input of the NOT logic gate 162 is connected to a start signal 164 from the control connector 104

and to the logic high voltage location 92 (via a resistor 163). The use of the start signal 164 as the clock port 160 input ensures that the controller unit will not operate until the practitioner and the patient are prepared to start the therapy. The clock port 160 is also connected to a diode 166 which, in turn, is  
5 connected to a clock port 168 of the second flip flop 170. The clock input 168 is further connected to ground via a resistor 172. A reset port 174 of the second flip flop 170 is not used while a D port 175 is connected to ground. An S port 173 of the second flip flop 170 is connected to a reset signal 177 of the control connector 104. A Q input port 176 is not used while a Q-bar input  
10 port 178 is connected via a resistor 180 to a base region 181 of a BJT 182. An emitter region 184 of the BJT 182 connects to the logic high voltage location 92. A collector region 186 is connected to the control connector 104.

Input to the NOT logic gate 188 is supplied by an output of an AND logic gate 192. One input to the AND logic gate 192 is connected to the logic  
15 high voltage location 92 (via a resistor 256), a Q input port 254 on a flip flop 230 (via a diode 258) and a Q-bar input port on a flip flop 216 (via a diode 260). A second input to the AND logic gate 192 is from a second AND logic gate 194. One input to the second AND logic gate 194 is from an output of a NOT logic gate 196. Input of the NOT logic gate 196 is connected to the logic  
20 high voltage location 92 (via a resistor 198) and to a stop signal 200 from the control connector 104. A second input to the AND logic gate 194 is connected to a D port 202 from a third flip flop 204.

The D port 202 is also connected to the decade counter 106. A Q input port 206 of the third flip flop 204 is not used and a reset port 208 is  
25 connected to ground. A Q-bar input port 210 is connected to an S port 214 of the fourth flip flop 216. A clock port 212 of the third flip flop 204 is connected to the oscillator 110.

The fourth flip flop 216 also contains a clock port 218 which is connected to the logic high voltage location 92 (via a resistor 220), a Q input  
30 port 222 of a fifth flip flop 224 (via a diode 226), via a diode 232, to an S port 228 of the sixth flip flop 230, the reset signal 177 and the S port 173 of the second flip flop 170. A reset port 234 is connected to a reset port 236 on the

fifth flip flop 224, a reset port 246 on the sixth flip flop 230 and to an output from a NOT logic gate 238. Input to the NOT logic gate 238 is connected to ground via a capacitor 240 and to the logic high voltage location 92 via a diode 242 or a resistor 244. The resistor 244 and the diode 242 are in  
5 parallel and thus two paths are provided from the logic high voltage location 92 to the input of the NOT logic gate 238.

A Q input port 248 on the fourth flip flop 216 is not used. A D port 250 on the fourth flip flop 216 is connected to the logic high voltage location 92.

A D port 266 on the fifth flip flop is connected to the logic high voltage  
10 location 92 while an S port 268 is connected to ground. A clock port 270 is connected to the one minute timer 108, the display connector 114 and the Q-bar input port 154 of the first flip flop 150.

A clock port 262 and a D port 264 of the sixth flip flop 230 are connected to the logic high voltage position 92. A Q-bar input port 262 of the  
15 sixth flip flop 230 is connected to the decade counter 106.

It will be understood by one skilled in the art that the logic high voltage location 92 and the laser high voltage location 80 need not be the same physical location. It is preferred that all the parts are connected to the same physical location to minimize on parts. As long as sufficient power (or  
20 voltage) to operate the parts is provided by the two high voltage locations 80 and 92, at each occurrence of the high voltage locations 80 and 92 (mentioned above), physical connection to the same location is not necessary. In a preferred embodiment, the housing unit is approximately 10 cm by 15 cm by 5 cm and thus is easily portable and provides laser therapy to  
25 an area larger than that traditionally treatable by single probe or wand lasers.

According to an alternative embodiment of the invention, a single laser may be substituted for the cluster laser where a device is used to disperse the light from the single source over the same area as the cluster laser. The dispersion device may be an irregular reflective device which may revolve to reflect the laser beam over the enlarged area. Alternatively, the dispersion  
30 device may be a fibre optic bundle which receives at the tight bundle end, the

laser beam. The bundle spreads outwardly at the other end to project the divided beam onto the enlarged area in a matrix array.

Although preferred embodiments of the invention have been described herein in detail, it will be understood by those skilled in the art that variations  
5 may be made thereto with departing from the spirit of the invention.

**CLAIMS:**

1. A portable phototherapy apparatus adapted for attachment to at least one body part and for providing therapy to said at least one body part comprising:
- 5
- i) means for providing dispersed photons over a predetermined surface area;
  - ii) means for attaching said means for providing dispersed photons to said at least one body part; and
  - 10 iii) control means for adjusting intensity and duration of said therapy.
2. The apparatus of claim 1 wherein said means for attaching said means for providing dispersed photons to said at least one body part comprises a backing on adjustable belt means.
- 15
3. The apparatus of claim 2 wherein said backing is flexible.
4. The apparatus of claim 1 further comprising an interlock connector.
- 20
5. The apparatus of claim 1 wherein said means for providing dispersed photons comprises at least one cluster laser pack having a plurality of cold-powered laser diodes.
- 25
6. The apparatus of claim 5 wherein said at least one cluster laser pack comprises from about 10 to about 20 laser diodes.
7. The apparatus of claims 5 or 6 wherein said laser diodes are selected from the group consisting of Class I, Class II and Class III laser diodes.
- 30
8. The apparatus of claims 5, 6 or 7 wherein said laser diodes emit at a wavelength between about 635 nm to about 905 nm.

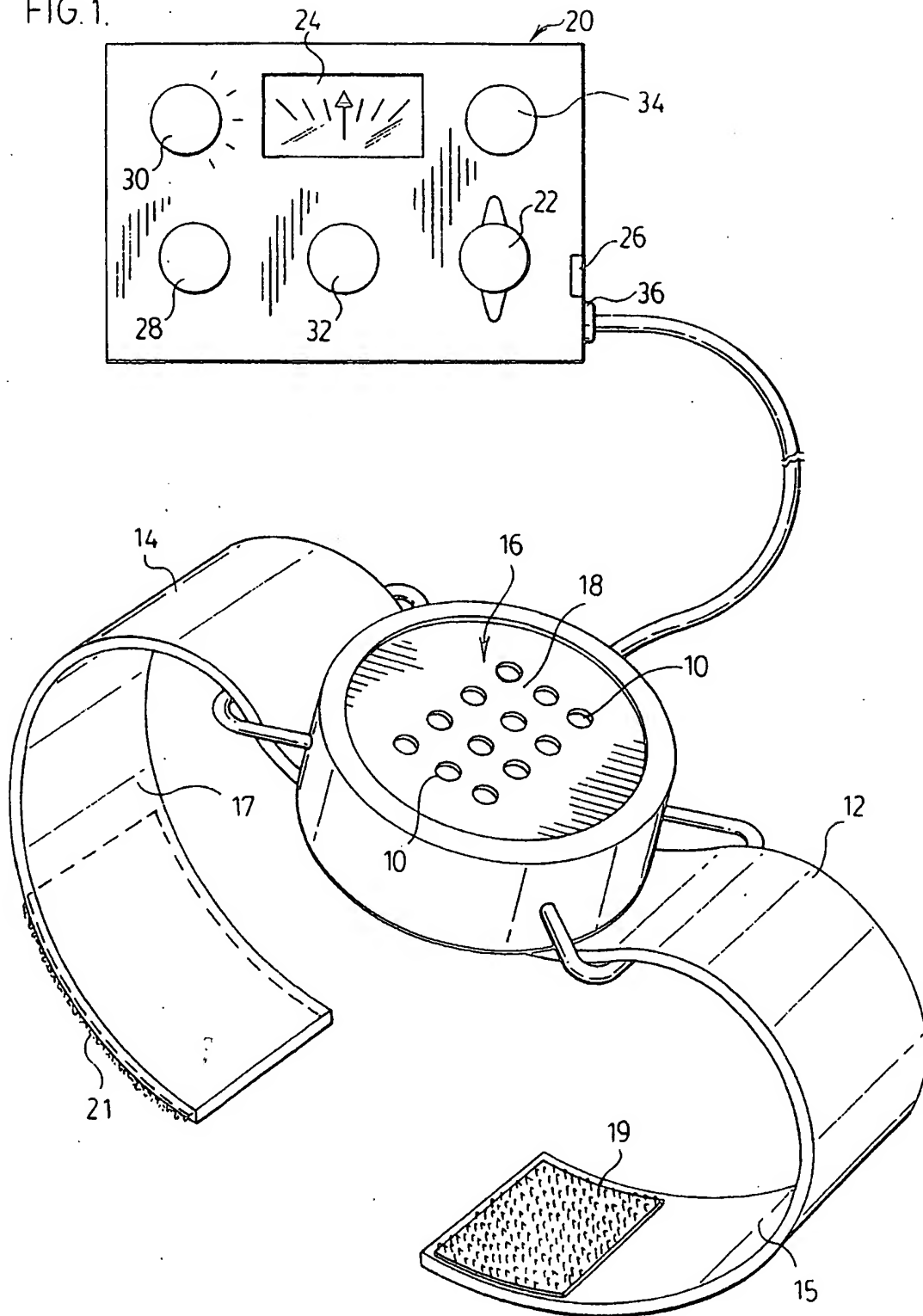
9. The apparatus of claims 5, 6, 7 or 8 wherein power of said laser diodes varies from about 1 mW to about 50 mW.
10. The apparatus of claim 1 wherein the means for providing dispersed photons comprises a single laser and a dispersion device.
11. The apparatus of claim 10 wherein said dispersion device is an irregular reflective device.
12. The apparatus of claim 10 wherein said dispersion device is a fibre optic bundle.
13. The apparatus of claim 1 wherein said control means comprises:
- i) an on/off switch;
  - ii) a timer;
  - iii) an emission indicator;
  - iv) a volume adjuster; and
  - v) a reset button.
14. The apparatus of claim 5 wherein each of said at least one cluster laser pack has an individual controller.
15. The apparatus of claim 5 wherein said at least one cluster laser pack is controlled by a single controller.
16. The apparatus of claim 15 wherein said single controller comprises:
- a control connector sending control signals;
  - a control logic box for translating said control signals and sending operation signals;
  - a microchip for accepting said operation signals and controlling said at least one cluster laser pack; and
  - means for providing power to said microchip.

17. The apparatus of claim 14 wherein said individual controller comprises:  
a control connector sending control signals;  
a control logic box for translating said control signals and  
sending operation signals;  
5 a microchip for accepting said operation signals and controlling  
said at least one cluster laser pack; and  
means for providing power to said microchip.
18. The apparatus of Claim 14 wherein each of said at least one cluster  
10 laser pack has an individual output.
19. The use of a plurality of cold powered laser diodes to stimulate  
photochemical reactions in an area to be treated, wherein said area to be  
treated is selected from the group consisting of wrist, elbow, shoulder, back,  
15 neck, ankle or knee.



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FIG. 1.



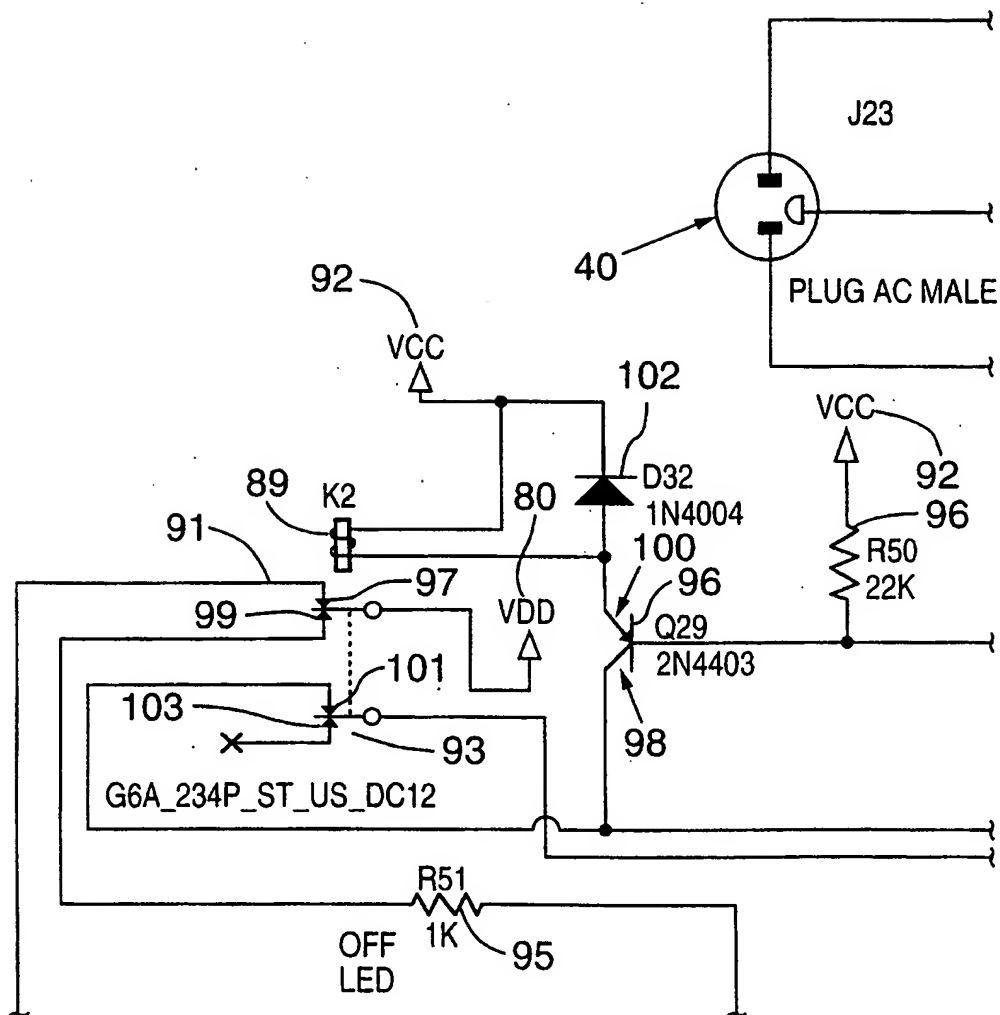


FIG.2A

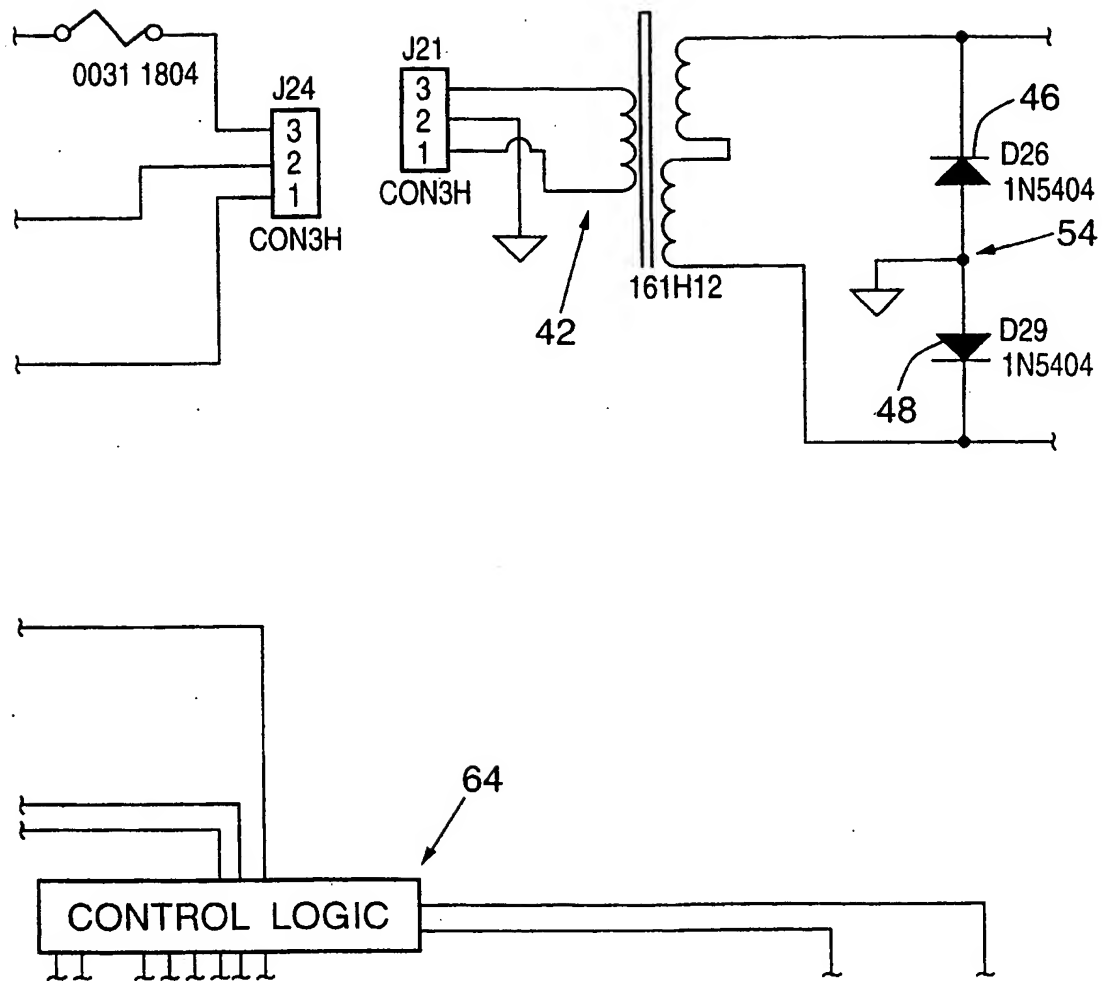


FIG.2B

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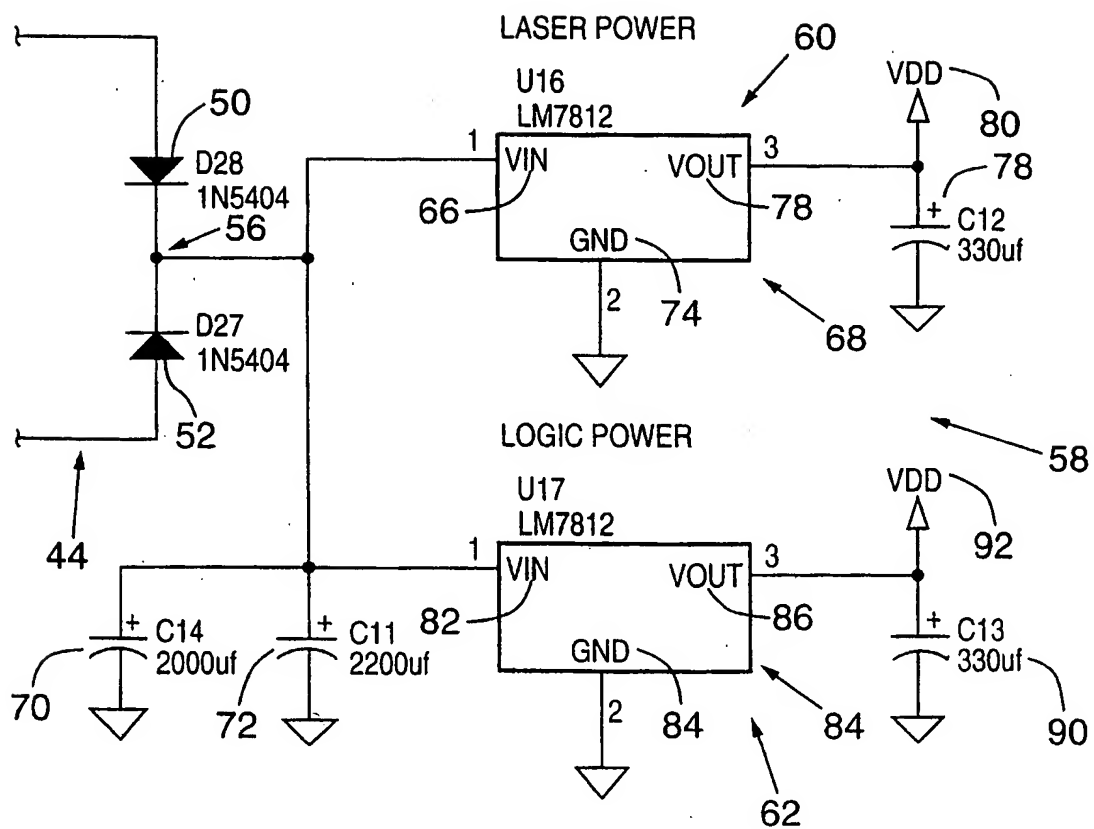


FIG.2C

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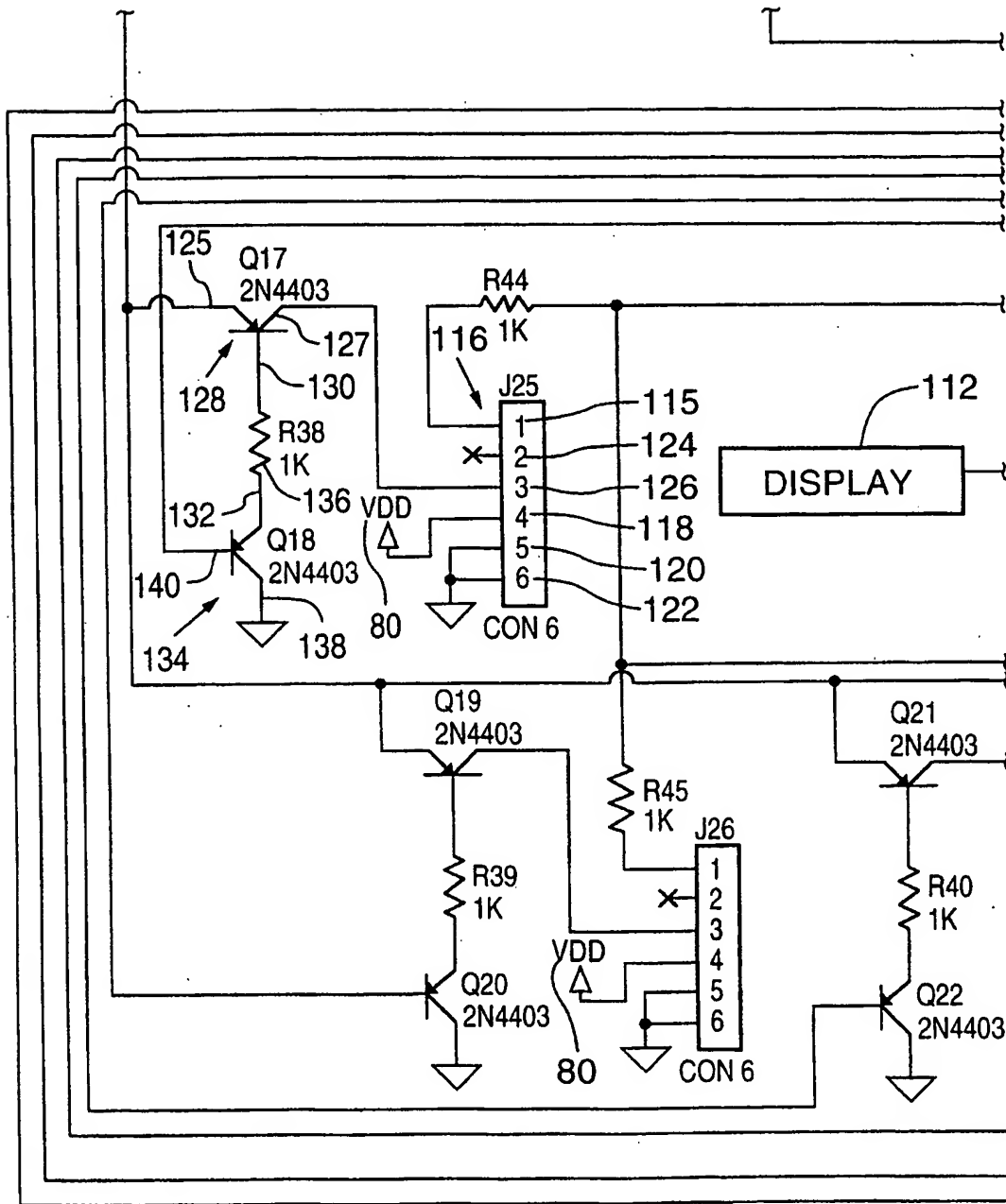


FIG.2D

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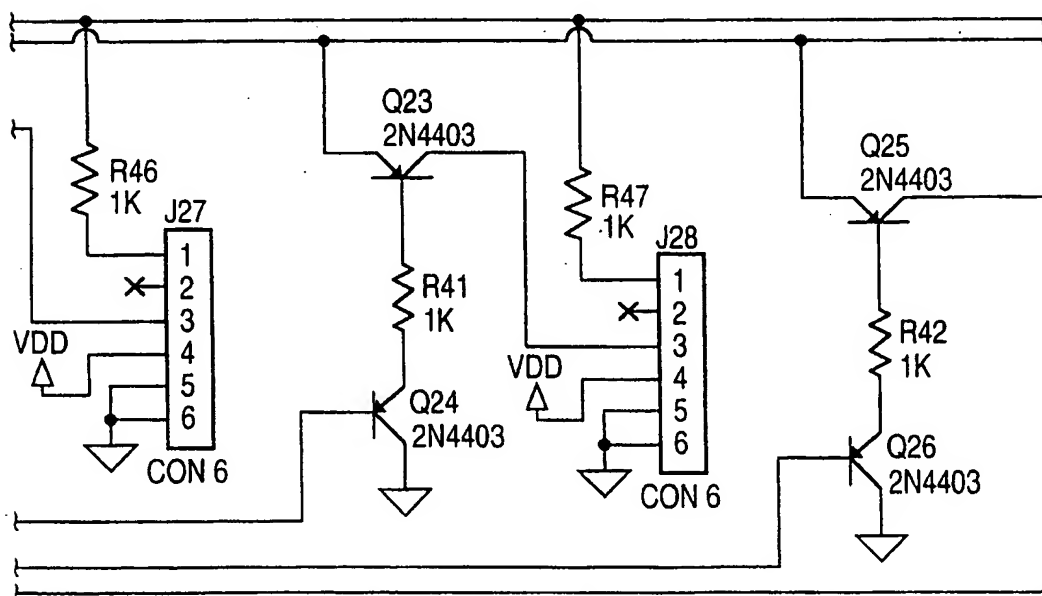
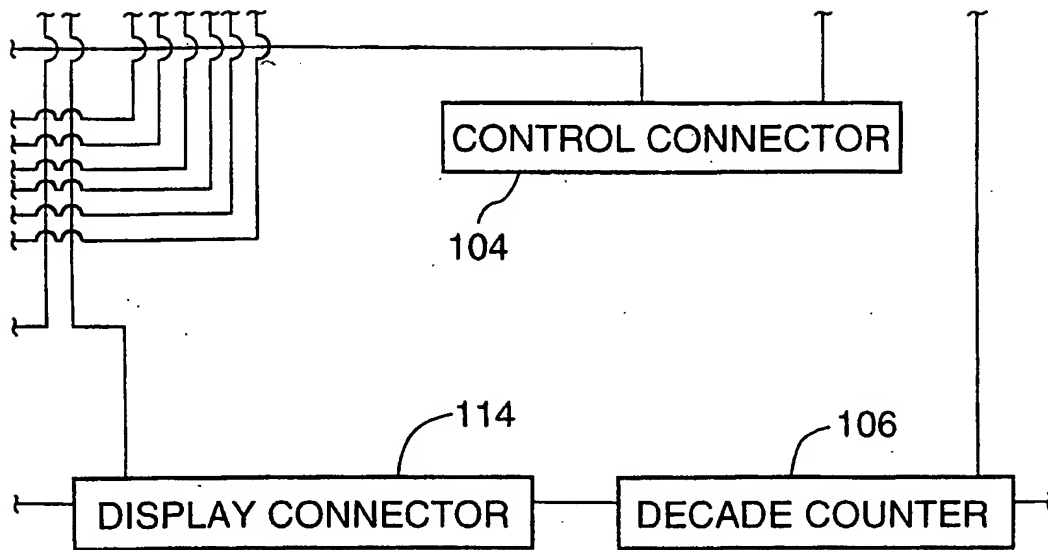


FIG.2E

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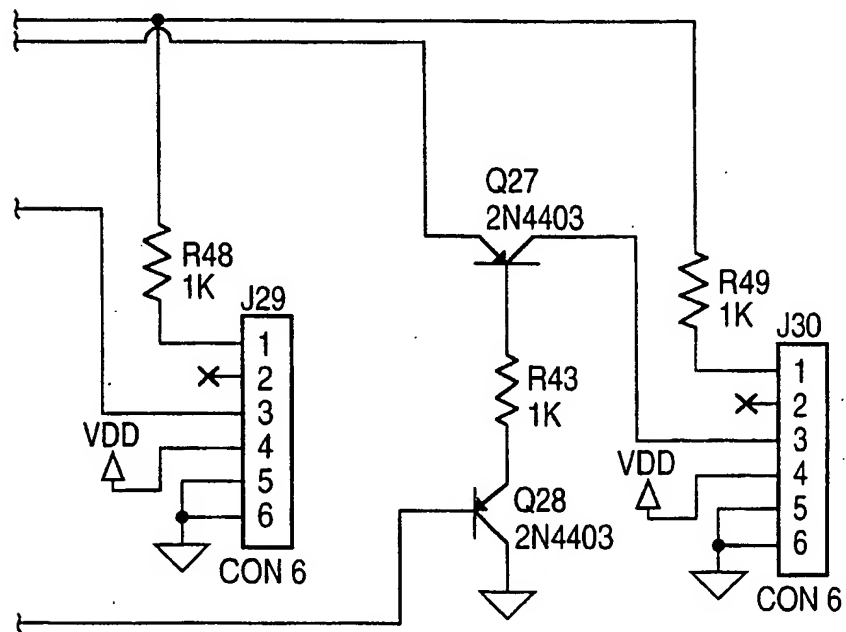
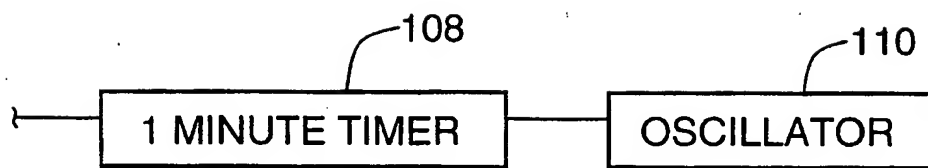


FIG.2F

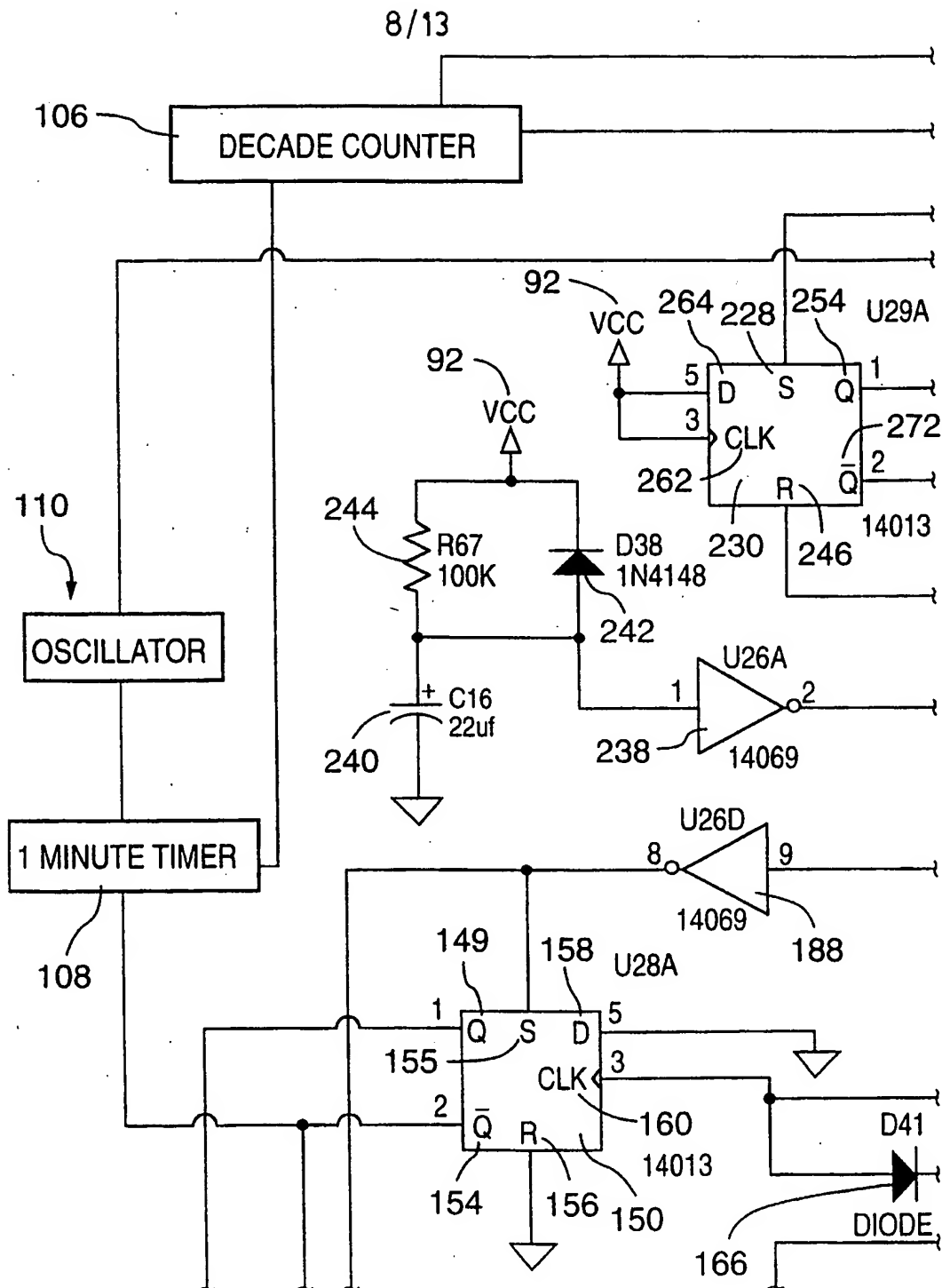


FIG.3A



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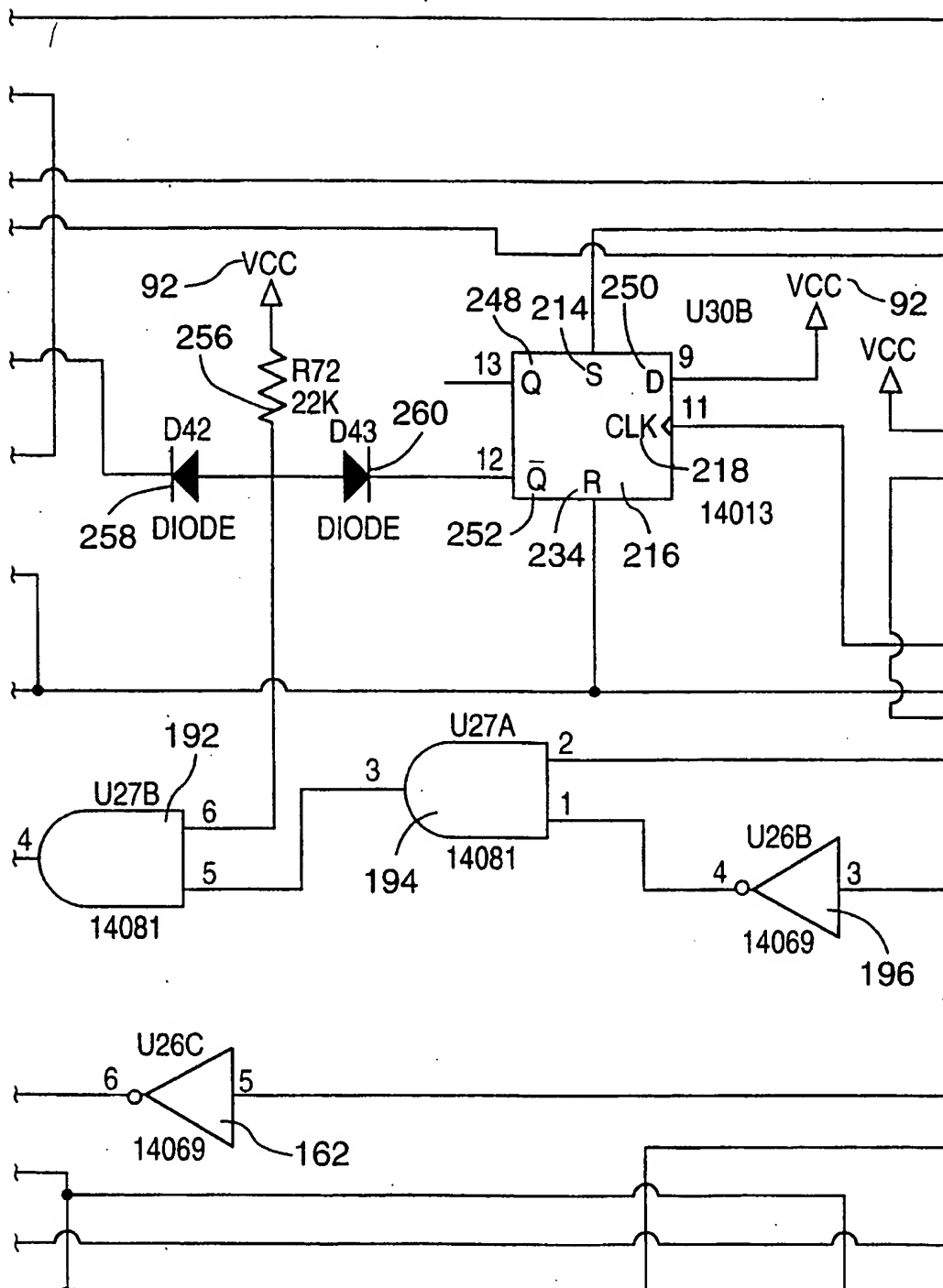


FIG.3B

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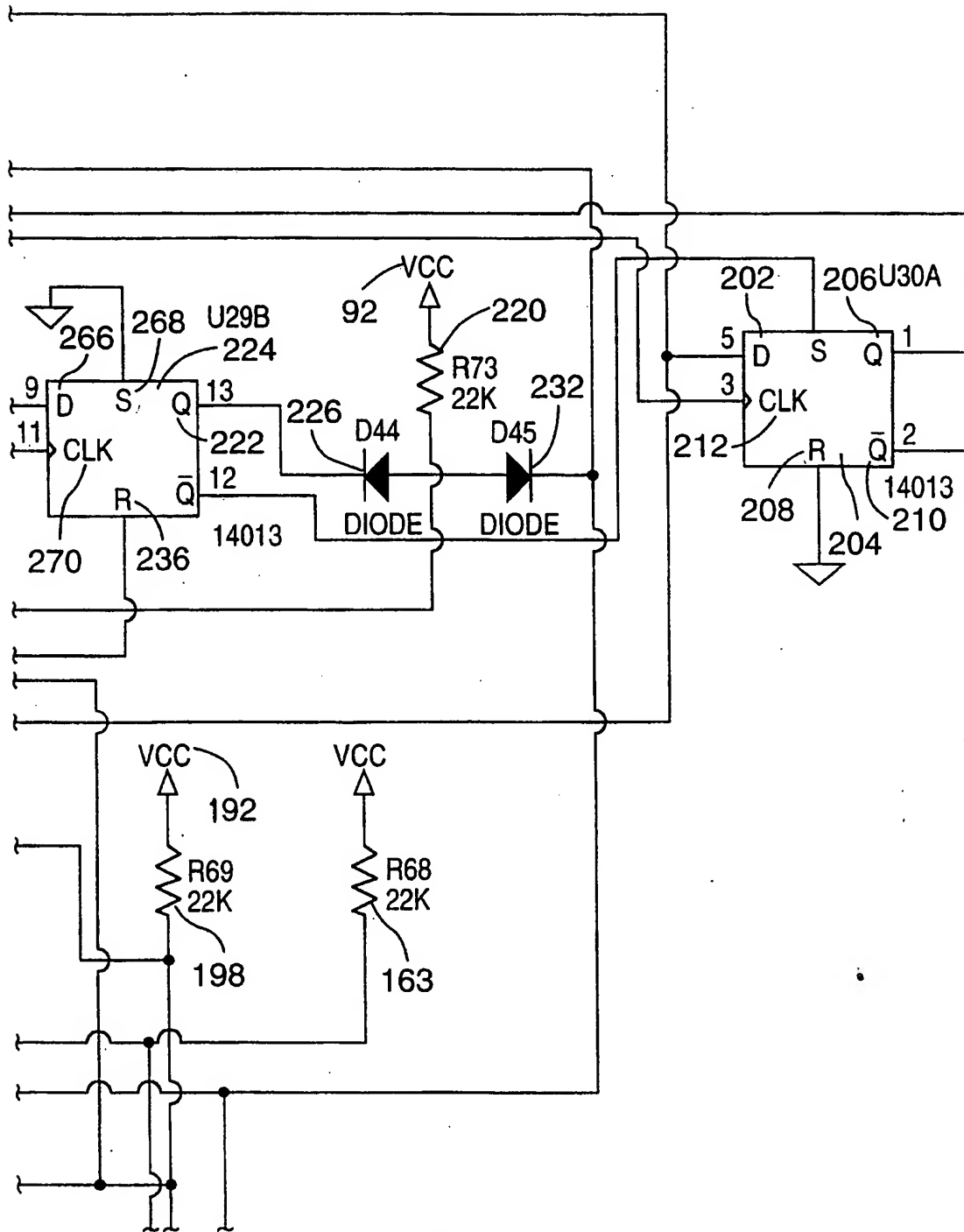


FIG.3C

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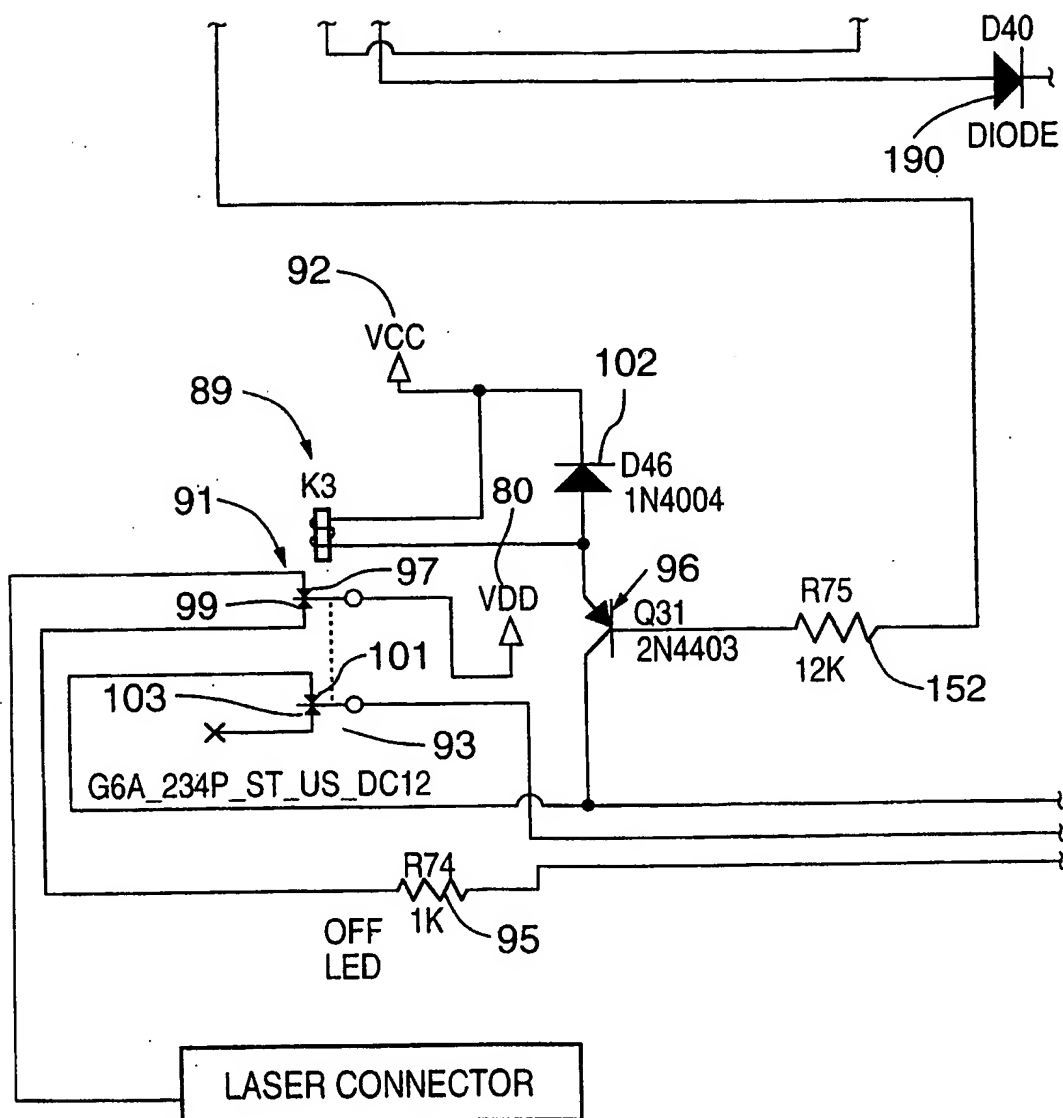


FIG.3D

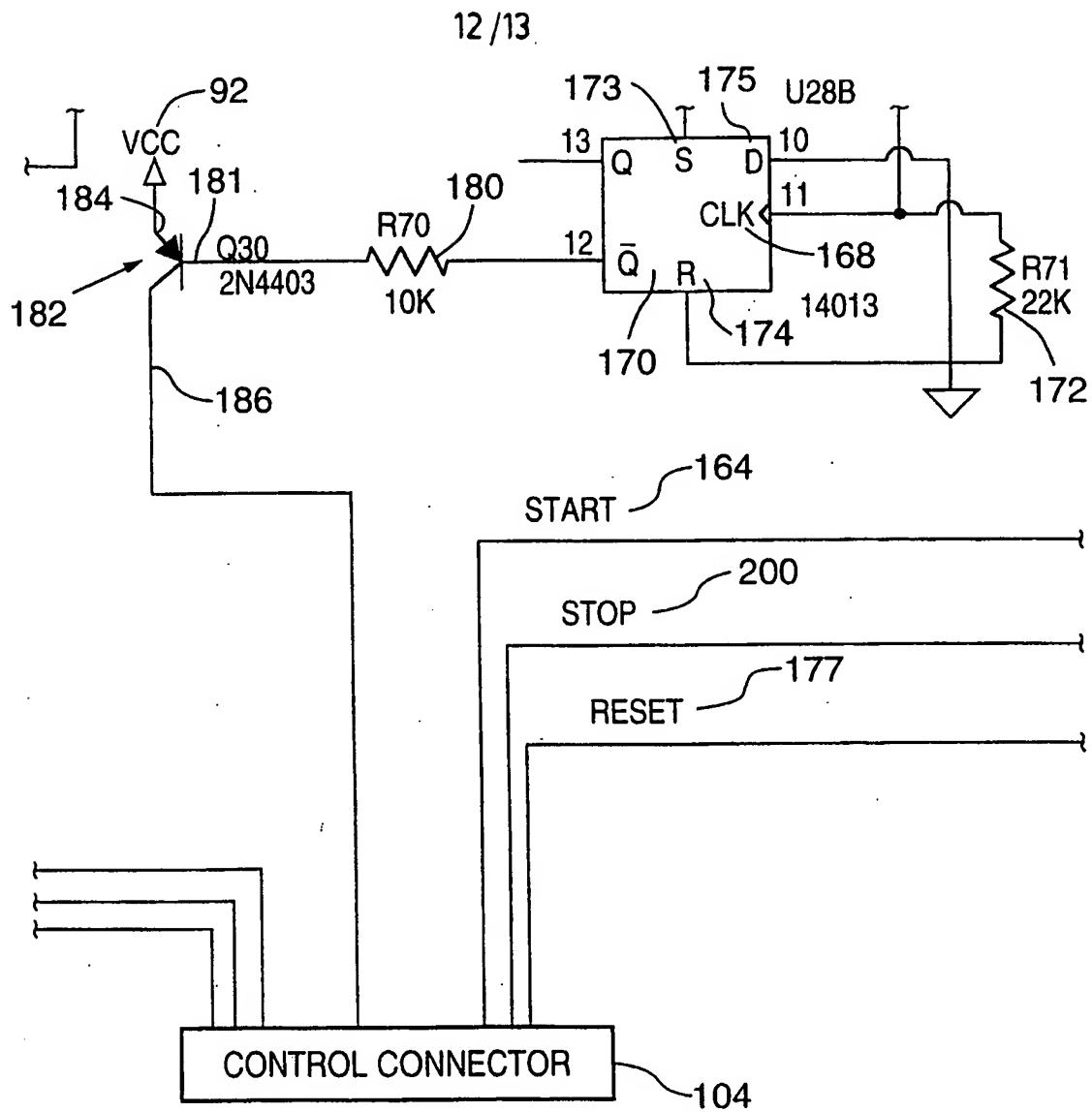


FIG.3E

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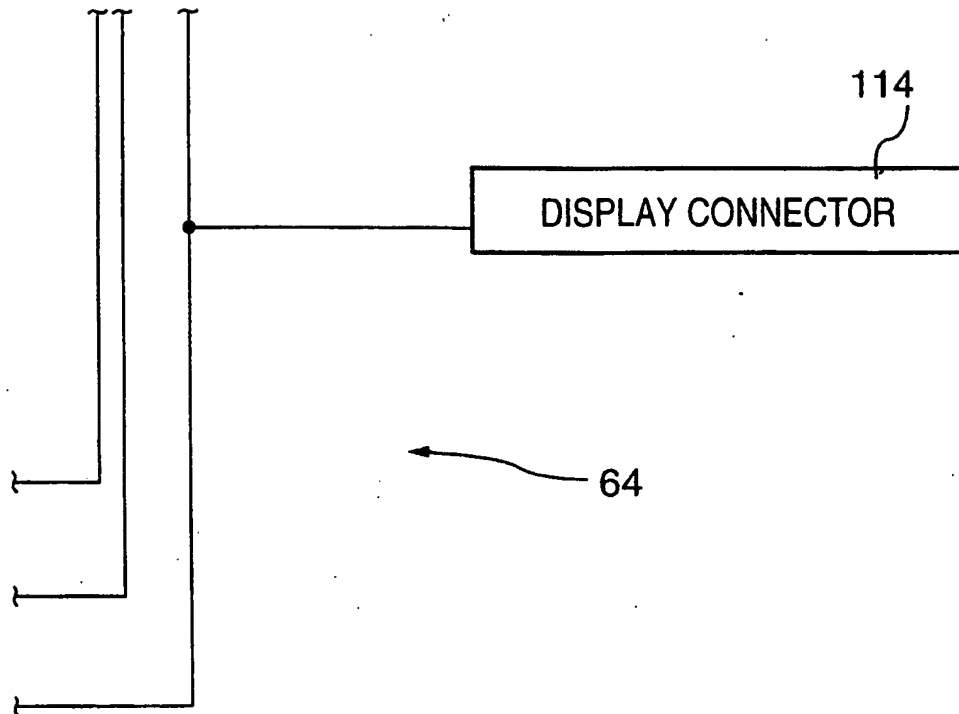


FIG.3F